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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,239	04/14/2005	Michel Fontes	BJS-3665-132	8759

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,239	FONTES ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,29,31,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 29, 31, and 47-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/08 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 10/17/2008. Claims 23, 29, 31, and 47-48 are pending in the applications, with claims 1-22, 24-28, 30, 32-46, and 49-50 having being withdrawn. Accordingly, claims 23, 29, 31, and 47-48 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

While the Examiner has already acknowledged applicant's arguments filed on October 17, 2008 in the Advisory Action, they are again addressed below for applicant's convenience.

Applicant's arguments that there is no motivation in Geffard to use vitamin C itself for therapy have been fully considered but are not found persuasive. Geffard

particularly teaches the use of polylysine conjugates such as vitamin C conjugates for the treatment of neurodegenerative diseases including Marie Charcot Tooth disease (CMT) (see col. 3, lines 7-8 and col. 5, lines 8-11). The Examiner would like to further point out that because Geffard did not explicitly teach the Vit. C-conjugate for Charcot Marie Tooth disease, the rejection was rendered obvious under 103 (a) rather than anticipatory. Moreover, the Examiner is well aware that the polylysine conjugate plays an important role in Geffard's invention as the Examiner previously stated on the record that that the polylysine conjugates helped in enhancing drug targeting to tissues (see Final Office Action, pg. 6, lines 1-3). Furthermore, the Examiner would like to point out that applicant's claims were previously directed to a method for treating CMT comprising vitamin C or a derivative thereof. The vitamin C polylysine conjugate of Geffard was considered by the Examiner as a derivative of vitamin C. Consequently, the Examiner assertst that Geffard did indeed render obvious applicant's method of treatment.

Applicant's arguments that Djoneidi and Austria do not cure the deficiencies of Geffard have again been fully considered. However, such arguments are not persuasive given that Geffard's teachings are directed to the use of vitamin C-polylysine conjugates for the treatment of neurodegenerative diseases which also include Charcot-Marie Tooth disease and thus render obvious applicant's invention. Djoneidi, in particular, was provided to demonstrate that Marie Charcot type 1 (CMT1a) was the major form of CMT and thus one of ordinary skill in the art would have found it obvious to treat such subtypes of patients as they make up the largest subpopulation of this

disease. Austria, on the other hand, was provided to demonstrate that ascorbic acid is unstable and tend to degrade while vitamin C derivatives such as magnesium ascorbyl phosphate and ascorbyl palmitate were found to be more stable. Thus, one of ordinary skill in the art would have found it obvious to substitute the aforementioned derivatives for the vitamin C of Geffard as they are more stable in solution. Consequently, the Examiner assertst that the rejections of record were indeed proper.

However, in view of applicant's amendment and cancellation of claims 23-34, 45-46, and 49-50, the rejections of record are hereby withdrawn. The following 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 29, 31, and 47-48 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Baxter et al. (U.S. 2002/0198236 A1) in view of Cupps et al. (U.S. 6486190).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Baxter et al. teach methods and compositions for modulating differentiation and proliferation of a cell utilizing compounds of formula I (see pg. 4, paragraph 0025). Particularly, Baxter et al. teach that the aforementioned method can be used as part of a therapeutic regimen in the treatment of Charcot Marie Tooth Disease (CMT; see pg. 40, paragraphs 0540-0548). Baxter et al. further teach that CMT1 is associated with demyelination or breakdown of myelin sheaths and that CMT1a is characterized by a duplication of a gene encoding a myelin protein called PMP-22 of treating neurodegenerative diseases, infections, traumatic or toxic neuropathies (see pg. 40, paragraph 0548). Importantly, Baxter et al. teach the pharmaceutical compositions can contain additional ingredients including water soluble antioxidants such as ascorbic acid and oil soluble antioxidants such as ascorbyl palmitate (see pg. 61, paragraphs 0665-0666).

Baxter et al. do not teach the exact unit dose of 1 to 6 grams of vitamin C or a derivative thereof.

Cupps et al, however, do teach that ascorbic acid antioxidants can be used at a dosage ranging from about 50 to about 10,000 mg (i.e. 0.050-10 g; see). Cupps et al. were provided to demonstrate that ascorbic acid can be used in particular dosages as antioxidants.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Baxter et al. to treat Charcot-Marie-Tooth disease since Baxter et al. teach the treatment of neurological disorders including Charcot-Marie-Tooth disease with compound of formula I in combination with antioxidants such as ascorbic acid or ascorbyl palmitate. Moreover, one of ordinary skill in the art would have found it obvious to administer the ascorbic acid in a dosage up to 10,000 mg (i.e. 10 g) since Cupps et al. teach that such antioxidants can be administered in such dosage range. Thus, given the teachings of Baxter and Cupps, one of ordinary skill would have been motivated to utilize the combination of compound of formula I along with ascorbic acid/ascorbyl palmitate to treat Charcot-Marie-Tooth disease with the reasonable expectation of providing a method with enhanced therapeutic effects in treating Charcot-Marie-Tooth disease.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

03/12/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617